

Attachment 3

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION**

R.J. REYNOLDS TOBACCO COMPANY;
SANTA FE NATURAL TOBACCO
COMPANY, INC.; ITG BRANDS, LLC;
LIGGETT GROUP LLC; NEOCOM, INC.;
RANGILA ENTERPRISES, INC.;
RANGILA, LLC; SAHIL ISMAIL, INC.; and
IS LIKE YOU INC.,

CIVIL ACTION NO. 6:20-cv-00176

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION; UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES; STEPHEN M. HAHN,
Commissioner of the United States Food and
Drug Administration; and ALEX AZAR,
Secretary of the United States Department
of Health and Human Services,

Defendants.

DECLARATION OF KIM REED

I, Kim Reed, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

Introduction & Issues to be Addressed

1. I am Executive Vice President for Sales at ITG Brands, LLC ("ITGB"). ITGB was founded in 2015 and today is the third-largest tobacco company in the United States and manufactures several leading brands of cigarettes (such as Winston, Kool, Salem, Maverick, Montclair, and USA Gold). I have a bachelor's degree from Wichita State University.

2. I have been employed by ITGB from 2019 to the present. In my current position, which I have held since June 2019, I have responsibility for management of the sales and marketing of all products in the ITGB portfolio.

3. In my role as Executive Vice President, I am a member of ITGB's Senior Leadership Team, with responsibility for assisting the development of ITGB's business strategy.

4. This declaration describes the numerous actions and significant costs that will be incurred by ITGB to comply with the new graphic-warning requirements imposed by the Food and Drug Administration ("FDA") detailed in the Final Rule entitled "Tobacco Products: Required Warnings for Cigarette Packages and Advertisements" on March 18, 2020, 85 Fed. Reg. 15638 (the "Rule"), issued under the Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31, 123 Stat. 1776 (2009) (the "Act").

5. The Rule requires significant changes by ITGB for its cigarette brands in terms of package design and operationally from the current warning regime in which there are four specified Surgeon General's warnings which must appear on the side of the pack (and elsewhere depending on the media or packaging) and rotate on a quarterly basis. 85 Fed. Reg. at 15688-90; Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200, 2201-02 (1984). By contrast, the Rule now mandates 11 new warnings (text and graphics) that will appear on the top 50% of the front and back of each pack (and elsewhere depending on the packaging or marketing media), imposes requirements regarding the appearance of the warnings on packaging (e.g., the required warning must be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation), and requires random and equal distribution of the warnings during manufacturing over the course of a year, within a commercially reasonable tolerance. 85 Fed. Reg. at 15688-90.

6. FDA recognizes that implementing changes of this magnitude is a significant undertaking and has provided fifteen months for manufacturers to do so from the publication date of the Rule. Specifically, the Rule's graphic-warning requirements apply to cigarette packaging manufactured on or after the effective date (fifteen months after the date the Rule is published) of June 18, 2021, and prohibits any cigarette packaging introduced into commerce on or after thirty days after that effective date that fails to bear the new warnings. 85 Fed. Reg. at 15694-95, 15709.

Implementation of Packaging Changes

7. As noted above, the Rule requires that ITGB changes the packaging graphics on every style of packaging and cartons for each of its cigarette products. ITGB has over 121 separate stock keeping units ("SKUs" or, colloquially, "styles") of cigarette products. These products are packaged in individual packs, cartons, and cases. As a result, ITGB will need to revise and produce over 121 distinct printed packaging (pack and carton) designs.

8. In order to comply with the Rule, ITGB must take the following steps:

9. First, ITGB employees, as well as affected suppliers must determine the steps and resources necessary to modify the current printing process to accommodate the number of packaging revisions required as well as to comply with the Rule's requirement relating to the random and equal display and distribution of the required warnings.

10. Second, to print the redesigned packaging, ITGB must purchase between 263 and 976 printing cylinder bases and additional tooling (e.g., cutting, creasing and embossing tools). The blank metal printing cylinders must each be engraved to apply the ink for the redesigned cigarette packaging. The cost of these cylinder bases, additional tooling and engraving is estimated to range from \$2.862 million to \$3.834 million. Some of these costs have already been incurred, but a large proportion of this amount has not yet been incurred. For example, the work to engrave

the cylinders will take at least five months and must begin within ten months after the Rule is published.

11. Third, ITGB must retain graphics design firms and/or marketing firms to create the redesigned packaging to work with the companies' brand teams. This will be time-consuming and expensive. Since the Rule significantly alters and severely limits the physical space for brand graphics and text on cigarette packaging, it is necessary to carefully evaluate these designs. This work must commence immediately. I estimate that it will take eight months to complete and require approximately 5,000 hours of employee and supplier time, and cost ITGB more than \$945,000.00, and must begin shortly after the final Rule is published.

12. Fourth, ITGB must then devote substantial employee time to review and approve the redesigned cigarette packaging and operational changes necessary to implement the Rule. The approval process will be extensive given the magnitude of the required packaging changes and the accompanying manufacturing and operational implications of the Rule. Numerous departments—including Consumer Marketing, Consumer Relations, Legal and External Affairs, Scientific and Regulatory Affairs, Manufacturing, Operations, Procurement, Product Development, and Trade Marketing, among others—will need to be involved, and this review and approval process will take eight months to complete. These activities are estimated to require at least 10,000 hours of employee time, collectively.

13. Finally, after modified packaging designs have been approved, the cylinders to print them must be engraved, as described above in paragraph 10.

14. Our ability to produce necessary inventory and compliant packaging, and the timing to do so, is further complicated and may be delayed by the ongoing COVID-19 public health emergency. The operations of many of the vendors, firms, and other third-parties on which we

rely for designing, supplying materials for, and printing the redesigned packages have been disrupted by both the pandemic and related state and local restrictions on their operations. The COVID-19 pandemic continues to rapidly evolve, and these third-parties and our business may be further impacted in ways that are highly uncertain and cannot be predicted with confidence.

Implementation of Other Marketing Changes

15. The Rule's revised warnings must be revised not only in packaging, but also in advertising. The Rule requires the top 20% of all advertising to contain the modified warning, thus existing brand advertising will also need to be revised. Most immediately, this impacts brand websites and retail point-of-sale advertising. For example, ITGB will need to redesign, print and replace numerous point-of-sale communications at each of approximately 102,000 contracted retailers. New warning compliant advertising will need to be designed, coded (for brand websites), or printed and installed (removing non-compliant advertising in the process) (for point of sale). This work is estimated to involve 182 hours of employee and supplier time and cost approximately \$945,000.00.

Deadline to Switch to Manufacturing of Redesigned Packaging

16. In order to produce the inventory necessary to comply with these deadlines, ITGB will need to begin manufacturing cigarettes in compliant packaging beginning at least three months prior to the Rule's effective date. If the Rule were invalidated after this point, ITGB would have an inventory of cigarettes carrying the invalidated warnings and reflecting costs exceeding \$61,680,000 in finished product because cigarette packages that fail to carry the correct FDA-mandated warning are "misbranded" under the Act and could not be lawfully sold. 85 Fed. Reg. at 15692. These "misbranded" cigarettes cannot be re-packaged, and the value of the reclaimed

tobacco is nominal. In addition, it is estimated that ITGB would incur costs of approximately \$4.25 million in unusable packaging materials.

Impact on Preferred Advertising and Promotion Strategies

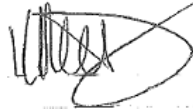
17. The Rule's required warnings for packaging, branding, and advertising will prevent ITGB from implementing preferred packaging, branding, advertising, and promotional strategies that ITGB would have otherwise pursued. The Rule's required warnings will also disadvantage ITGB relative to its larger competitors by limiting the amount of information ITGB can provide to adult smokers about its products, including by limiting the branded portion of the product packaging that will be visible to adult smokers on retail shelves.

Effect of Temporary Stay

18. Although a four-month temporary stay of the effective date of the Rule (including interim compliance dates) has been granted, ITGB has already begun the steps described in paragraphs 9-12 and 15 above for compliance, and must continue with these steps now to meet the Rule's deferred effective date. For example, ITGB has begun working with the companies' brand teams to create and evaluate the redesigned packaging, a process that will take at least thirteen months and must begin immediately in order to ensure compliance with the effective date. For the other steps described above, while the stay might result in a brief, four-month delay in implementing those steps, ITGB will still incur these harms and costs, absent preliminary injunctive relief.

Summary and Conclusion

19. For the reasons described above, the logistical, design and planning issues to implement the Rule on a nationwide basis are extraordinary. Absent relief from the Court, ITGB will have no choice other than to continue with efforts to implement the Rule, as detailed above, during the period while the legality of the Rule is determined.



Kim Reed
Executive Vice President, Sales
ITG Brands, LLC

May 14, 2020